IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
NORFOLK DIVISION

LIFENET HEALTH,

Plaintiff,

v.

LIFECELL CORPORATION,

Defendant.

Civil Action No. 2:13cv486/HCM-DEM

DEFENDANT LIFECELL CORPORATION'S MEMORANDUM IN SUPPORT OF ITS RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW UNDER FED. R. CIV. P. 50(b)

Defendant LifeCell Corporation respectfully submits this brief in support of its renewed motion for judgment as a matter of law ("JMOL") under Federal Rule of Civil Procedure 50(b). In the alternative, if the Court does not grant JMOL in Defendant's favor, it should grant a new trial for the reasons stated herein as well as those in Defendant's motion under Rule 59.

LEGAL STANDARD

Under Rule 50(b), a renewed JMOL motion may be granted where the evidence presented at trial would not provide a reasonable jury a legally sufficient evidentiary basis to find for the prevailing party on the issue. Fed. R. Civ. P. 50(b); *see Konkel v. Bob Evans Farms, Inc.*, 165 F.3d 275, 279 (4th Cir. 1999). "A Rule 50(b) motion should be granted if a district court determines, without weighing the evidence or considering the credibility of the witnesses, that substantial evidence does not support the jury's findings." *Id.* In considering a JMOL motion, the evidence is examined in the light most favorable to the non-moving party. Nonetheless, "the court should review all of the evidence in the record," and may rely on uncontradicted and unimpeached evidence supporting the moving party to grant the motion. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

ARGUMENT

I. Defendant Does Not Directly Infringe Any Asserted Claim.

Plaintiff presented only one theory of liability: direct infringement of claims 1-4, 7-8, and 10 of the '200 patent. Tr. at 1732:19-1733:12. Defendant could be liable for direct infringement only if its products and processes meet each and every requirement of these claims. Because Defendant's products and processes do not do so, JMOL of no infringement should be granted.

All of the asserted claims require that "said one or more plasticizers are not removed from said/an internal matrix of said plasticized soft tissue graft prior to transplantation into a human." PTX 1 at 24:10-55. The Court recognized "that the nonremovable aspect applies *at the time of the product being transplanted*," Pre-Trial Conference Tr. at 3:11-15 (emphasis added), that the "claim language states that the accused graft is one where plasticizers are not removed prior to transplantation; the final act *is transplantation*, and the graft can *only infringe upon the patent if there is no removal of plasticizers*," D.I. 298 at 11 (emphases added). A product or process therefore cannot *directly* infringe any asserted claim unless and until a plasticized soft tissue graft has been transplanted into a human where plasticizer was not removed from the graft's internal matrix prior to transplantation. The record evidence is not legally sufficient to support a finding that *Defendant*'s making, using, offering for sale, or selling of the accused products meets the "not removed … prior to transplantation" requirement—nor that Defendant's accused products and processes meet additional claim requirements—and the Court should therefore enter JMOL that Defendant does not directly infringe any asserted claim.

A. Defendant Does Not Make, Use, Sell, Offer For Sale, Or Import Products That Directly Infringe Any Of The Asserted Apparatus Claims (Claims 1-4).

Claims 1-4 of the '200 patent purport to be apparatus claims, which claim a *particular product*. PTX 1 at 24:10-31. Defendant could not directly infringe any asserted apparatus claim

unless *Defendant itself* makes, uses, offers for sale, sells, or imports an apparatus that meets all of the requirements of the claim, including that "said one or more plasticizers are not removed from said/an internal matrix of said plasticized soft tissue graft prior to transplantation into a human." *See, e.g.*, *Centillion Data Sys., LLC v. Qwest Commc'ns Int'l, Inc.*, 631 F.3d 1279, 1286-88 (Fed. Cir. 2011). Defendant therefore could not directly infringe any asserted apparatus claim unless *Defendant* makes, uses, offers for sale, sells, or imports a plasticized soft tissue graft that *has been transplanted* into a human without removal of plasticizer from the graft's internal matrix prior to transplantation.

Defendant should be granted judgment of non-infringement as a matter of law on all asserted apparatus claims because there is no evidence that *Defendant* has transplanted any of its products into a human without removing plasticizer from the product's internal matrix prior to transplantation. In fact, there is no evidence that *Defendant* ever transplants grafts into humans, nor is there any evidence that *Defendant* ever prepares grafts for transplantation into humans. Tr. at 903:15-904:1 (Bachrach). Those procedures are performed by independent surgeons and their assistants. Tr. at 577:2-7, 853:11-18, 857:7-858:17 (Erdmann); 903:15-18 (Bachrach).

At the time Defendant makes, uses, sells, or offers for sale its accused products, the products *cannot* meet the "not removed . . . prior to transplantation" requirement and thus cannot meet each and every requirement of the apparatus claims. Whether a graft made or sold by Defendant could ultimately lead to a product that meets each and every requirement of the claims depends on how the graft is later prepared and used by independent surgeons and their assistants. It is not until Defendant's grafts are used in a particular way, by medical professionals exercising their medical judgment, that there could even potentially be an apparatus that meets the "not

removed . . . prior to transplantation" requirement. But *Defendant* does not take actions necessary to create an apparatus that meets every requirement of the asserted claims.

Under controlling precedent, Defendant thus cannot be liable for direct infringement. *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 424 F.3d 1293 (Fed. Cir. 2005), is instructive. There, a patent claimed an apparatus with components "operatively joined" to bone. The Federal Circuit explained that "the limitation—the anchor seat being in contact with bone—is absent until the screw and anchor are put in place during surgery," *id.* at 1311; that surgeons were responsible for the "operatively join[ing]," *id.* at 1311-12; and that "because [the manufacturer] does not itself make an apparatus with the 'interface' portion in contact with bone, [the manufacturer] *does not directly infringe*," *id.* at 1311 (emphasis added); *accord Centillion*, 631 F.3d at 1286 (no direct infringement because Defendant never used the claimed system).

Here, as in *Cross Medical*, the conduct of surgeons would be necessary for creation of the claimed apparatus, and thus "if anyone makes the claimed apparatus, it is the surgeons, who are … not agents of [the manufacturer]." 424 F.3d at 1311; *see* D.I. 298 at 11 (the "claim language states that the accused graft is one where plasticizers are not removed prior to transplantation; the final act *is transplantation*, and the graft can *only infringe upon the patent if there is no removal of plasticizers*") (emphases added). With respect to agency, there is no record evidence that surgeons and their assistants act under the direction and control of Defendant when they prepare grafts for transplantation and transplant them into humans.[1] Accordingly, any acts by surgeons and their assistants that might make an infringing apparatus cannot be attributed to Defendant. *See Akamai Techs., Inc. v. Limelight Networks, Inc.*, 692 F.3d 1301, 1307 (Fed. Cir. 2012) (en

[1] Plaintiff never even pleaded or raised in any manner such a theory of the case, nor requested a jury instruction on this issue.

banc) ("Absent an agency relationship between the actors or some equivalent, however, a party that does not commit all the acts necessary to constitute infringement has not been held liable for direct infringement . . . ."), *rev'd on other grounds, Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111 (2014).

In addition, Plaintiff did not present evidence of any single instance of a surgeon transplanting an accused product into a human without removing any plasticizer from the internal matrix prior to transplantation, let alone Defendant doing so. Thus, Plaintiff failed to prove that *anyone* infringed an asserted claim. In any event, because Plaintiff did not offer any evidence of an actual instance in which all elements of the claim were satisfied by Defendant, there is no substantial evidence to support the verdict of infringement.

Moreover, even if Plaintiff had presented evidence that surgeons and their assistants directly infringed the asserted apparatus claims through their use of the accused products, the only way Defendant could be liable for infringement would be under a claim of *indirect* patent infringement pursuant to 35 U.S.C. § 271(b) or § 271(c). But Plaintiff never pleaded indirect patent infringement, and a claim of indirect infringement, which would require proof of different elements than direct infringement, was never presented to or considered by the jury. *See, e.g.*, *Commil USA, LLC v. Cisco Sys., Inc.*, 720 F.3d 1361, 1367 (Fed. Cir. 2013) ("A finding of inducement requires both knowledge of the existence of the patent and 'knowledge that the induced acts constitute patent infringement.'"); *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2067 (2011) ("[A] violator of § 271(c) must know that the combination for which his component was especially designed was both patented and infringing.") (citation omitted).

Thus, there is not legally sufficient evidence to support the jury's verdict of infringement of any apparatus claim, and JMOL of no infringement should be entered on those claims. *See*

Singer v. Dungan, 45 F.3d 823, 827 (4th Cir. 1995) (A "movant is entitled to judgment as a matter of law if the nonmoving party failed to make a showing on an essential element of his case with respect to which he had the burden of proof.") (internal quotations omitted).

B. Defendant Does Not Perform A Process That Directly Infringes Any Of The Asserted Method Claims (Claims 7-8 and 10).

Claims 7-8 and 10 are method claims, which claim a particular *process*. Defendant could not directly infringe any asserted method claim unless *Defendant itself* performs *all* steps of the claimed methods. When no *single* party performs *all* of the steps of a claimed method, but multiple parties together perform all the steps, alleged infringement is said to be "divided" and, subject to only a narrow exception not applicable here; none of the parties can be liable for direct infringement. *See, e.g.*, *Aristocrat Techs. Austl. PTU Ltd. v. Int'l Game Tech. Inc.*, 709 F.3d 1348, 1362 (Fed. Cir. 2013) (finding no infringement because "no single actor performs all of the steps of the claimed methods"); *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014) ("[T]here has simply been no [direct] infringement of the method in which respondents have staked out an interest, because the performance of all the patent's steps is not attributable to any one person.").

Defendant should be granted JMOL of no infringement on all asserted method claims because there is no evidence that *Defendant* performed the step of transplanting an accused product into a human without removing plasticizer from the graft's internal matrix prior to transplantation, nor that *Defendant* directed and controlled the conduct of another party who did so. As noted above, there is no evidence that *Defendant* ever transplants grafts into humans, nor that *Defendant* ever prepares grafts for transplantation. Those procedures are performed by independent surgeons and their assistants, who exercise their medical judgment. Thus, even if all elements of the method claims had been practiced (and there is no evidence they were),

infringement would be divided because Defendant, as the manufacturer of grafts, allegedly performs only certain steps of the claimed method (*e.g.*, "impregnating a cleaned, soft tissue graft"), and the step of transplanting Defendant's graft into humans without removing plasticizer from the internal matrix prior to transplantation would be performed (if at all) by independent surgeons and their assistants, as the users. Tr. at 577:2-7 (Kaplan); 853:11-18, 857:7-858:17 (Erdmann); 903:15-18 (Bachrach).

Under controlling precedent, Defendant therefore cannot be liable for direct infringement of the asserted method claims. For example, in *Muniauction, Inc. v. Thomson Corp.*, where patent claims were directed to auctioning municipal bonds using an Internet web browser, the Federal Circuit faced the issue of "whether the actions of at least the bidder and the auctioneer may be combined under the law so as to give rise to a finding of direct infringement by the auctioneer." 532 F.3d 1318, 1329 (Fed. Cir. 2008). The court held they could not, explaining that "where the actions of multiple parties combine to perform every step of a claimed method, the claim is directly infringed only if one party exercises 'control or direction' over the entire process such that every step is attributable to the controlling party, i.e., the 'mastermind.'" *Id.* Similarly, in *Aristocrat*, the Federal Circuit found no direct infringement because "no single actor perform[ed] all of the steps of the claimed methods." 709 F.3d at 1362. The court explained that "to be liable for direct infringement, [the patentee had to] exercise direction or control over a player playing the game." *Id.* Because the patentee did not have any agency relationship with the players, it could not be held vicariously liable for infringement. *Id.* at 1363.

As explained above, there is no evidence that independent surgeons and their assistants are acting as agents of Defendant when they prepare grafts for transplantation and transplant them into humans, or that their actions are under Defendant's direction and control. Nor did

Plaintiff even plead or present such a theory. Thus, there is no basis for attributing actions of surgeons and their assistants to Defendant. Because Defendant does not practice all elements of any asserted method claim, Defendant should be granted JMOL of no infringement of the asserted method claims.

C. Under The Proper Construction Of "Plasticizers Are Not Removed . . . Prior To Transplantation," The Evidence Is Legally Insufficient To Support A Finding That Defendant Infringed The Asserted Claims.

In the *Markman* Order, the Court construed the term "said one or more plasticizers are not removed from said/an internal matrix of said plasticized soft tissue graft prior to transplantation into a human," which is a requirement in all asserted claims, as having "no further construction needed." D.I. 123 at 14. The Court supplied that same construction to the jury. In the course of the litigation, however, it became clear that construction of that term was *needed* because the parties had significant disputes about: (1) the amount of removal required to fall outside the claim limitation (removal of some plasticizer versus removal of all plasticizer); (2) the relevant timing of removal (prior to transplantation versus prior to packaging); and (3) whether there is an intent requirement for the removal (any deliberate action that has the effect of removing plasticizer versus only actions that are intended to remove plasticizer).

Prior to trial, the Court consistently interpreted the claim term to require that "*no* plasticizer is removed" at any time *prior to transplantation*. Markman Tr. at 62:1-3; D.I. 123 at 10-11; Pre-Trial Conference Tr. at 3:11-15. The Court also initially drew a line separating deliberate actions that result in removal of plasticizer (which the Court indicated would be outside the claim term), D.I. 123 at 11, from inadvertently "losing some [plasticizer] in the formulation process," Markman Tr. at 68:15-23, or having some plasticizer "escape during formulation or transplantation" (which the Court indicated would still be permitted by the claim term), D.I. 123 at 11. Later, however, the Court indicated that it interpreted the term to exclude

only actions that *intentionally* remove plasticizer (*i.e.*, an action done "for the purpose of removing plasticizers"). Tr. at 1625:3-9. It is legal error to construe a claim term to require a specific mental state. *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1353 (Fed. Cir. 2001). If the claim term were construed to require specific intent, it would also be indefinite because infringement would depend on a particular user's mental state in preparing a graft for transplantation. Moreover, importing an intent requirement has no support in the '200 patent's specification, prosecution history, or claim language.

The legally correct interpretation of the claim term would require that there is no partial or full removal of plasticizers from the internal matrix prior to transplantation. *See* D.I. 62 at 14-16. That interpretation provides clear "metes and bounds" and does not require inquiry into an actor's intent or mental state. Under a legally correct interpretation, there is no evidence to support any conclusion other than that Defendant's products are prepared for transplantation—by surgeons and their assistants—with a step that removes some of the plasticizer from the graft's internal matrix (*i.e.*, the soak in saline removes plasticizer). Tr. at 853:11-18, 857:7-858:17 (Erdmann). Because the record does not reflect sufficient evidence showing that each claim limitation, as properly construed, is satisfied, Defendant is entitled to JMOL of no infringement. *See, e.g., Research Plastics, Inc. v. Fed Packaging Corp.*, 421 F.3d 1290, 1297 (Fed. Cir. 2005); *Forest Labs., Inc. v. Abbot Labs.*, 239 F.3d 1305, 1309 (Fed. Cir. 2001). Additionally, the record evidence is not legally sufficient for Plaintiff to support *its burden* of proving the plasticizer removed from Defendant's products is *not removed from the internal matrix*, as discussed below.

Even under a construction requiring a "deliberate action," there is no evidence supporting a conclusion other than that Defendant's products are prepared for transplantation with a deliberate action that does, in fact, remove a substantial amount of plasticizers (*i.e.*, the soak in

saline solution). The soak in saline solution is a deliberate step, and has the effect of removing plasticizer. *See, e.g.*, DTX 256; DTX 365; Tr. at 934:1-9494:19, 946:25-949:8, 995:4-1001:23 (Dahlgren); 1116:9-1117:15, 1127:16-1131:5, 1135:19-1136:11 (Badylak); Wolfinbarger Dep. Tr. at 96:15-99:3 (admitting that rinsing in saline would remove plasticizers in as little as "two seconds"). Plaintiff offered no evidence disputing Defendant's testing, which showed a soak in saline of even two minutes removes substantial amounts of plasticizer from the decellularized tissue (which is the "internal matrix")[2] and that a longer soak removes even more of these materials. DTX 256; Tr. at 1130:6-16 [redacted]) (Badylak); DTX 365; Tr. at 996:21-997:15 ([redacted]) (Dahlgren). In fact, Plaintiff's expert conceded that the surfaces of the accused grafts are composed of "internal matrix" material, *see* Tr. at 579:18-580:1, and undisputed evidence establishes that in a soak of at least two minutes, plasticizer is removed from within those surfaces and from the interior of the graft, DTX 256; DTX 365; Tr. at 1130:6-16 (Badylak). Further, Plaintiff offered no evidence that the accused products have *ever* been implanted into a patient without the instructed soak.

Moreover, it was *Plaintiff*'s burden to prove direct infringement by a preponderance of the evidence, which required Plaintiff to prove the "not removed . . . prior to transplantation" limitation is met by Defendant's products and processes. While that required Plaintiff to prove a

[2] The accused products are decellularized tissue matrices. PTX 112; PTX 115; PTX 240. As Plaintiff's own witnesses and documents concede, after a graft is decellularized, all that remains is the extracellular matrix, DTX 183; Tr. at 227:9-14 (Qin) ("when we implant the tissue it's basically just the matrix.")—which is the same as what the '200 patent refers to as the "internal matrix," Tr. at 486:6-11 (Kaplan) ("[T]he extracellular matrix is essentially the same thing as the internal matrix.").

negative, that is the claim language the patentee chose to use to overcome a Patent Office rejection. Further, the uncontradicted record evidence is that significant amounts of plasticizer come out of Defendant's products after a two-minute soak in saline solution, which is the minimum protocol set forth in Defendant's instructions for use. DTX 292; DTX 293; DTX 256; DTX 365. Despite this uncontradicted evidence and its burden to prove the negative, Plaintiff did not present (or even conduct) any testing, data, computation, or modeling to support its contention that *none* of the significant amount of [redacted] that is removed from the decellularized tissue matrices (*i.e.*, the accused products) in a saline soak, DTX 256; DTX 365, is removed from the internal matrix of the graft. *See* Tr. at 584:5-585:1 (Kaplan).

Instead, Plaintiff impermissibly shifted its burden of proving a negative ("not removed from . . . internal matrix") to Defendant by telling the jury it was *Defendant's* burden to prove that the plasticizer removed in the "rinse study" was from the internal matrix. Tr. at 1778:6-1779:14 (Songer). But it was *Plaintiff's* burden to prove that the plasticizer that is removed during a saline soak is *not* from the internal matrix, and there is no legally sufficient evidence of record to support such a conclusion. Plaintiff offered nothing but bare, conclusory expert testimony, which could not carry its burden of proof. *See Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1319-20 (Fed. Cir. 2006) (holding an expert's "conclusory testimony" unsupported by "examinations or tests of the actual accused products" insufficient to prove infringement).

Moreover, Plaintiff's infringement position is inconsistent with the '200 patent's specification, which teaches that soaking in saline is a way to remove plasticizer from a plasticized soft tissue graft. PTX 1 at 12:8-16. The specification teaches, for example, that a rinse in saline solution for approximately one hour will "remove as much plasticizer as possible."

Id. The specification also states that even a "brief" wash will remove plasticizer from the surfaces of a graft, *id.*, which Plaintiff's expert conceded are composed of "internal matrix." *See* Tr. at 579:18-580:1; *see supra*, n.2. Plaintiff's bare expert testimony is thus contrary to the clear teachings of the '200 patent that (1) in the art, a rinse with or soak in saline solution is a way to remove plasticizers from the internal matrix of a graft; and (2) it is not possible to remove *all* plasticizer. *Id.* Defendant's instructions for use direct that the accused products be soaked in saline solution for a minimum of two minutes and up to four hours, DTX 292; DTX 293, which is clearly a step of removal according to the disclosures of the '200 patent, PTX 1 at 12:8-16.

Plaintiff's infringement argument is also inconsistent with the prosecution history of the '200 patent. The inventors of the '200 patent were required to add the limitation that plasticizer is "not removed" to overcome a rejection over Cavallaro. DTX 463 at FH_0001132-33. If a saline rinse or soak does not sufficiently remove plasticizer to fall outside the asserted claims, then the added limitation would not have distinguished Cavallaro, and the '200 patent would impermissibly read on Cavallaro. The patent claims cannot be construed to allow the patentee to recapture subject matter that was clearly disclaimed to secure the patent in the first place.

Plaintiff's infringement position also rests on an incorrect claim construction that Plaintiff argued to the jury. In particular, Plaintiff argued to the jury that plasticizers are "contained in" the internal matrix only if they are chemically bonded to certain components of the internal matrix in particular ways—and, correspondingly, that molecules of plasticizer can be "removed from" the internal matrix only if they had been chemically bonded to those components in those ways. *See, e.g.*, Tr. at 463:14-467:24 (Kaplan); 1774:21-1775:3, 1775:13-1776:4 (Songer). From this, Plaintiff's expert asserted that only so-called "tightly bound" and "loosely bound" plasticizers are "contained in" the internal matrix, and that removal of so-called

"free" or "bulk" plasticizer from a graft is permitted by the claims. But there was no basis in the Court's construction, or the '200 patent, to contend that "contained in" and "removed from" had these specialized meanings. Neither the '200 patent's claims nor the specification recognize any distinction between so-called "free" plasticizer, "loosely bound" plasticizer, and "tightly bound" plasticizer, and the claims do not permit removal of one type of plasticizer ("free" or "bulk") but not others. If anything, the fact that a "plasticized soft tissue graft" was construed to mean a tissue "composed of an internal matrix where *free* and loosely bound waters of hydration in the tissue have been replaced with one or more plasticizers," D.I. 123 at 14 (emphasis added), means that "free" water *is* in the internal matrix, and so too would be "free" plasticizer. Further, the "internal matrix" refers to "the intercellular substance of such soft tissue including for example ligaments and tendons, including collagen and elastin fibers and base matrix substances," D.I. 123 at 7, yet Dr. Kaplan admitted on cross-examination that plasticizers are not actually contained in collagen fibers or these other components. Tr. at 582:10-583:1. Plaintiff's very theory of infringement was contrary to the plain meaning of the claim language and the proper construction of "not removed,"[3] and cannot support a verdict of infringement.

Applying the proper construction of the "not removed . . . prior to transplantation" limitation, no reasonable jury could find infringement. The evidence indisputably shows "plasticizers" are removed from the internal matrix of Defendant's products during the pre-transplantation saline soak of at least two minutes directed by the instructions for use; Plaintiff

[3] Even under Plaintiff's theory, there is no legally sufficient evidence of infringement. The undisputed evidence shows that significant quantities of plasticizer are removed from the decellularized tissue that constitutes the accused products, which even Dr. Kaplan admits is at least partially composed of internal matrix. Tr. at 544:11-18. Plaintiff presented no credible evidence from which a reasonable jury could conclude that none of the plasticizer removed by the pre-implantation soak is removed from the internal matrix, and it was Plaintiff's burden to do so to prove infringement. As such, Defendant is entitled to JMOL.

simply did not offer legally sufficient evidence to prove the negative that the removed plasticizer was not removed from the internal matrix. *See* DTX 256; DTX 365; Tr. at 220:16-21, 227:9-14 (Qin); 486:6-11, 564:8-565:10, 576:3-14, 586:4-16 (Kaplan); 785:3-23 (Harper); 934:1-944:19, 946:25-949:8, 995:4-1001:23 (Dahlgren); 1116:20-1117:15, 1127:16-1131:5, 1136:2-11 (Badylak). Accordingly, Defendant is entitled to JMOL of no infringement on all claims.

D. The Record Evidence Is Legally Insufficient To Support A Finding That Defendant's Products And Processes Meet Other Elements Of The Claims.

The record evidence is not legally sufficient to permit a reasonable jury to conclude that any of Defendant's accused products satisfy additional elements of the asserted claims as well. *First*, to establish the accused products meet the "plasticized soft tissue graft" limitation, Plaintiff bore the burden to prove by a preponderance of the evidence that in Defendant's products and processes the "free and loosely bound waters of hydration in the tissue have been replaced with one or more plasticizers." D.I. 123 at 14. The uncontradicted evidence, however, is that [redacted][4]

For reasons explained in the *Markman* proceedings, Markman Tr. at 37:9-38:23, under a proper construction of "plasticized soft tissue graft," Plaintiff would have needed to prove that the accused products had residual moisture content comparable to traditional dehydrated products, while the evidence shows the accused products are preserved in a hydrated state. *See, e.g.*, DTX 154; DTX 257; Tr. at 1145:15-23, 1149:8-17 (Badylak). The '200 patent teaches removal of water to preserve tissue (replacing the water with plasticizer to reach a low water

[4] Plaintiff also did not present evidence comparing the mechanical properties of the accused grafts to the mechanical properties of normal hydrated tissue, which would be necessary to determine if those properties are "similar" as required by the Court's construction. *See* Tr. at 1345:14-21 (Badylak). Plaintiff's expert, Dr. Kaplan, admitted he did not attempt to determine the mechanical properties of the accused products or the mechanical properties of normal hydrated tissue, nor did he do a comparison. *See* Tr. at 565:13-567:22, 568:2-23, 569:3-12.

content), *see, e.g.*, PTX 1 at 9:8-17, while Defendant uses a fundamentally different approach in which a mixture of materials allows Defendant to preserve the tissue while it remains hydrated. *See* DTX 216; DTX 257; Tr. at 804:3-25, 806:12-807:3 (Harper); 1321:2-15 (Badylak). Plaintiff offered no legally sufficient evidence from which it could reasonably be inferred that in the accused products the free and loosely bound waters of hydration had been replaced.[5]

Second, there is no legally sufficient evidence that Defendant's accused products satisfy the "suitable for implantation into a human without rehydration" requirement of claim 4. The evidence shows the accused grafts require a soak in saline of at least two minutes prior to implantation. DTX 293; DTX 491; DTX 783; PTX 72; Tr. at 852:4-863:3 (Erdmann); 905:2-10, 910:1-19 (Bachrach). If free and loosely bound waters of hydration had been replaced by one or more plasticizers, as required by the "plasticized soft tissue" limitation of the independent claims, then a soak in saline would have the effect of rehydrating the graft, contrary to the requirements of claim 4. Indeed, Plaintiff's own documents describe the accused products as requiring rehydration. *See* DTX 154; Tr. at 419:3-19, 420:10-14 (Brame).

Third, there is no legally sufficient evidence that, under a proper construction of the "transplantation into a human" terms, Defendant's accused porcine-derived products infringe. As explained in *Markman* proceedings, "transplantation into a human" in the '200 patent should be construed to require tissue derived from humans, *see* Def. Markman Br. (D.I. 62) at 20-22; Markman Tr. at 46:10-49:14, while Strattice and Conexa are derived from porcine dermis tissue.

Finally, for reasons explained in the *Markman* proceedings, Markman Tr. at 70:13-71:18,

[5] Plaintiff's expert also argued that free water is not part of the internal matrix. Tr. at 465:6-11, 499:18-500:2. If this argument were consistent with the '200 patent's disclosure and claim language (it is not), it would mean the accused grafts are not "plasticized soft tissue grafts," because there is no "free water" in the internal matrix that could be replaced by plasticizer.

76:13-15, under a proper construction of the terms "impregnating" and "incubating," there would be no legally sufficient evidence that those claim limitations of claims 2, 7, 8, and 10 are satisfied with respect to the accused products or processes. The inventors of the '200 patent acted as their own lexicographer and expressly defined "impregnating" in the specification to mean use of "processing conditions which result in filling the internal matrix of a bone graft with a plasticizer composition." PTX 1 at 6:55-58. Their explicit definition should control, *see, e.g.*, *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1356 (Fed. Cir. 2014) ("the patentee's lexicography must govern the claim construction analysis"); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls."), and it would have required Plaintiff to prove the accused products underwent processing which results in filling the internal matrix of a bone graft with a plasticizer composition. Similarly, the specification defines "incubating" as requiring certain forms of processing a bone graft. Neither of these limitations would be met by the processing of the accused products, which are soft tissues.

II. The Asserted Claims Are Invalid.

A. Apparatus Claims 1-4 Are Indefinite Because They Impermissibly Recite An Apparatus And A Method For Using The Apparatus.

Apparatus and method claims "are directed toward different classes of patentable subject material under 35 U.S.C. § 101" and it is well-settled that the distinction between these types of subject matter should not be "blurred." *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1344 (Fed. Cir. 2008). The Federal Circuit has accordingly held that product claims that include limitations on how the product is used are invalid as indefinite. *See, e.g.*, *IPXL Holdings, L.L.C. v. Amazon.com, Inc.*, 430 F.3d 1377, 1384 (Fed. Cir. 2005).

Judgment of invalidity as a matter of law should be granted as to claims 1-4 because they

impermissibly combine a claim to a product (a "plasticized soft tissue graft") with a limitation on how the product is used ("plasticizers are not removed . . . prior to transplantation"). Although the Court addressed this issue in denying summary judgment, Defendant respectfully submits that the Court misapplied Federal Circuit precedent in declining to hold the apparatus claims indefinite, as the claims at issue are properly analogized to *IPXL* and are clearly distinguishable from the claims at issue in *HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270 (Fed. Cir. 2010), which did not involve a claim term directed to user actions.

In *IPXL*, a claim was indefinite because "it is unclear whether infringement … occurs when one creates a system that allows the user to change the predicted transaction information or accept the displayed transaction, or whether infringement occurs when the user actually uses the input means to change transaction information or uses the input means to accept a displayed transaction." *IPXL*, 430 F.3d at 1384. The problem arose because the phrase "wherein … the user uses" was "directed to user actions, not system capabilities." *In re Katz Interactive Call Processing Patent Litig.*, 639 F.3d 1303, 1318 (Fed. Cir. 2011). The same is true here; the "not removed" limitation is directed to user actions (transplantation without plasticizer having been removed prior to the transplantation), making it "unclear when infringement would occur." *H-W Tech., L.C. v. Overstock.com, Inc.*, 758 F.3d 1329, 1336 (Fed. Cir. 2014).

In contrast, the claims in *HTC* recited a mobile station for use with a network and described the functions performed by that network, not functions performed by the mobile station. As the Federal Circuit explained, the claims recited "the mobile station—which must be used in a particular network environment," 667 F.3d at 1277, and thus it could be definitively determined at the time the claimed apparatus was made or sold whether it infringed. The same reasoning cannot apply here because, as the Court observed, "the nonremovable aspect applies *at*

the time of the product being transplanted," Pre-Trial Conference Tr. at 3:11-15 (emphasis added), and the "claim language states that the accused graft is one where plasticizers are not removed prior to transplantation; the *final act* is *transplantation*, and the graft can *only infringe upon the patent if there is no removal of plasticizers*," D.I. 298 at 11 (emphasis added). Here, it is impossible to determine at the time of Defendant's manufacture or sale whether the accused products infringe. Indeed, much of the challenge in construing the "not removed" limitation stems from the fact that the inventors tacked onto apparatus claims a limitation on how a graft may be used for transplantation. Similarly, the direct infringement issue with respect to the asserted apparatus claims, described in detail above, illustrates why a "mixed" claim is indefinite. With such claims, one cannot ascertain *who* is infringing the claims and *when* infringement occurs, as in *IPXL*.

B. The Asserted Claims Were Anticipated By Werner And Duran.

Judgment as a matter of law should be granted that the asserted claims were anticipated by Werner (DTX 633) and Duran (DTX 631). A claim is anticipated if a single prior-art reference disclosed, expressly or inherently, each of the claim's elements. *Krippelz v. Ford Motor Co.*, 667 F.3d 1261, 1265 (Fed. Cir. 2012). Both Werner and Duran disclosed each and every limitation of the asserted claims, either expressly or inherently. Based on the evidence, no reasonable jury could find the asserted claims of the '200 patent are not anticipated.

1. Werner anticipated the asserted claims.

At trial, Defendant's expert explained how Werner discloses every limitation of the asserted claims. *See* Tr. at 1180:2-1190:7, 1196:24-1201:25, 1252:6-1253:3. In response, Plaintiff disputed only whether Werner met the "cleaned" and "plasticized soft tissue graft" limitations. *See* Tr. at 1526:6-14. The record evidence is not legally sufficient to support Plaintiff's arguments as to either limitation. Although the Court addressed anticipation by

Werner on summary judgment, the trial record reveals that the evidence is legally insufficient to find Werner does not anticipate the '200 patent.

At trial, Plaintiff's expert admitted that Werner discloses a process that removes "some of the cell components." *Id.* at 1522:5-25, 1562:6-10; *see also id.* at 1183:21-1186:3, 1591:22-1592:23 (Badylak). That meets the requirements of a "cleaned" soft tissue. As the Court has stated, its "claim construction does not require that all of the cellular elements be removed." D.I. 298 at 22.[6] To the extent that the Court in its summary judgment order construed "cleaned" to require no capability of transmitting diseases, D.I. 298 at 22, importing such an additional requirement into the claims would be error, and in any event there was no evidence presented at trial that Werner's grafts would transmit disease (such as "mad cow" disease).

Werner also discloses a "plasticized soft tissue graft" that is made in the same way as taught in the '200 patent's specification. Werner used the same concentration of the same plasticizer (30% glycerol) as the examples of the '200 patent, which are plasticized soft tissues. *See, e.g.*, PTX 1 at 22:32-24:2, DTX 633 at 2:49-68. The conclusory testimony of Plaintiff's expert that Werner does not disclose a "plasticized soft tissue graft" flatly contradicts the '200 patent's disclosure that soaking a soft tissue graft with 30% glycerol will result in a plasticized soft tissue graft, Tr. at 1554:4-9, 1555:13-17 (Kaplan), and "[e]xpert opinions that are contrary to admissions in the specification do not create a factual issue." *Smith & Nephew, Inc. v. Rea*, 721 F.3d 1371, 1380 n.6 (Fed. Cir. 2013); *see PharmaStem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1361-62 (Fed. Cir. 2007). Werner, which discloses soaking a soft tissue graft with the same plasticizer (glycerol) at the same concentration (30%) as the '200 patent, will inherently

[6] Plaintiff also admitted during claim construction that removal of any cellular components is sufficient to create a "cleaned" graft. Pl. *Markman* Br. (D.I. 65) at 14.

have the characteristics of the "plasticized soft tissue graft." *See, e.g.*, Tr. at 1181:6-1182:16 (Badylak); 1555:10-21 (Kaplan). Although Dr. Kaplan initially asserted that Werner's "mechanical properties are altered significantly from native tissue" based on a supposed "increase in tensile strength by a factor of 1.7 to 7.0," *id.* at 1524:15-18, 1525:3-6, he conceded on cross-examination that these data did not compare Werner's plasticization of the tissue to normal hydrated tissue, *id.* at 1552:22-1553:2, and thus are irrelevant to whether Werner disclosed "mechanical properties, including the material, physical, and use properties, of the tissue product [that] *are similar to those of normal hydrated tissue*." No reasonable jury could conclude that Werner did not anticipate the asserted claims.

2. Duran anticipated the asserted claims.

Defendant's expert also explained how Duran disclosed every limitation of the asserted claims. *See* Tr. at 1253:17-1256:3, 1261:6-1276:20. Plaintiff again disputed only two limitations: whether Duran disclosed a "cleaned" graft and a "plasticized soft tissue graft." *See* Tr. at 1534:21-1535:4. There is no legally sufficient evidence to support Plaintiff's arguments that either element was missing, or that Duran was not prior art to the '200 patent.

Dr. Kaplan admitted that Duran discloses processing soft tissue with an organic solvent (acetone) that would remove some cellular components. Tr. at 1570:8-14. As discussed above, this is all that is required by the "cleaned" limitation. Thus, there is insufficient evidence to permit any conclusion other than that Duran discloses a "cleaned" soft tissue graft. Tr. at 1267:24-1268:24 (Badylak).

The evidence also established conclusively that Duran disclosed a "plasticized soft tissue graft." Dr. Kaplan admitted that Duran teaches a soft tissue graft preserved in glycerol with unaltered collagen fiber orientation and mechanical properties similar to normal hydrated tissue—requirements of the Court's construction. Tr. at 1568:4-1569:1. Plaintiff only disputed

whether Duran teaches replacing free and loosely bound waters of hydration. *Id.* at 1567:13-23, 1569:2-6. But Duran teaches treating soft tissue with up to 50% glycerol, which constitutes a treatment with a "suitable plasticizer" at a concentration that, according to the '200 patent and Dr. Kaplan's own testimony, would necessarily replace free and loosely bound waters of hydration in soft tissue. *Id.* at 464:24-465:3, 484:5-485:4. Dr. Kaplan's assertion that even in the presence of 30% or 50% glycerol, the tiny amount of heparin in Duran, DTX 631 at 3:25-27, was "going to change what glycerol is going to do" because it is "a polysaccharide," Tr. at 1533:1-1534:19, contradicted the disclosure of the '200 patent. The '200 patent discloses that the internal matrix itself contains polysaccharides, PTX 1 at 3:9-12, 5:16-21, and that even 30% glycerol acts as a plasticizer in the presence of polysaccharides, PTX 1 at 22:50-23:5, 23:35-58. "Expert opinions that are contrary to admissions in the specification do not create a factual issue." *Smith & Nephew*, 721 F.3d at 1380 n.6; *PharmaStem Therapeutics*, 491 F.3d at 1361-62.

Finally, the record evidence cannot support a conclusion other than that Duran was prior art to the '200 patent. To antedate the Duran reference, Plaintiff bore the burden to produce evidence that the inventors conceived of all claimed features before Duran's filing date (June 24, 1998) and then "exercised reasonable diligence in later reducing that invention to practice." *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993). To prove conception, Plaintiff needed to provide evidence that "a definite and permanent idea of an operative invention, including every feature sought to be patented, [was] known." *Sewall v. Walter*s, 21 F.3d 411, 415 (Fed. Cir. 1994). "The conceived invention must include *every feature* of the subject matter claimed in the patent." *Ethicon, Inc. v. U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998) (emphasis added). Plaintiff, however, offered no evidence from which a reasonable jury could conclude either that the inventors conceived of all elements of the asserted claims before June 30, 1998, or

that the inventors exercised reasonable diligence from a purported earlier date of conception in reducing their alleged soft tissue graft invention to practice. For example, there is no evidence of conception before June 30, 1998 of a plasticized soft tissue graft in which the one or more plasticizers are not removed prior to transplantation.

C. Judgment As A Matter Of Law Should Be Granted That The Asserted Claims Were Obvious In Light Of The Prior Art.

The evidence adduced at trial establishes that the asserted claims were obvious as a matter of law under 35 U.S.C. § 103. "A patent is invalid for obviousness 'if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1237 (Fed. Cir. 2010) (quoting 35 U.S.C. § 103). There are four factual issues underlying the legal question of obviousness: (1) the level of ordinary skill in the pertinent art; (2) the scope and content of the prior art; (3) differences between the prior art and the claims at issue; and (4) evaluation of any relevant secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). The ultimate determination of obviousness, however, is an issue of law. *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997); *see id.* at 1485 (affirming district court's grant of JMOL of obviousness, overturning contrary jury verdict).

A claim is obvious when, as here, "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). Cleaning of soft tissue grafts while maintaining their structural integrity was well known to those skilled in the art prior to June 30, 1998. PTX 1 at 9:21-37; Tr. at 1283:13-1284:3, 1290:9-16 (Badylak); 1569:7-9 (Kaplan). The evidence also shows "plasticizing" grafts with glycerol was well known to those skilled in the art

prior to June 30, 1998. *Id.* at 1051-1060, 1187:5-9 (Badylak). The evidence conclusively establishes that, in light of the prior art, the claims would have been obvious to a person of ordinary skill in the art (POSA)[7] in June 1998 in light of (1) Werner combined with the knowledge of a POSA; (2) Duran combined with the knowledge of a POSA; (3) Werner in combination with Goldstein or Livesey; and (4) Duran in combination with Goldstein or Livesey. The evidence shows that a POSA would have been motivated to combine the preservation techniques disclosed in these references with cleaning techniques well-known in the art, and would have expected success in doing so. *See, e.g.*, Tr. at 1284:5-1285:5, 1287:11-14, 1288:5-20, 1289:15-24, 1292:2-1293:15 (Badylak).

Indeed, Plaintiff admitted cleaning soft tissue was known to POSAs prior to the '200 patent, *e.g.*, Tr. at 1283:14-1284:3, 1290:9-16 (stipulations), and Dr. Kaplan admitted "there would have been reasons for someone who was skilled in the art to clean a soft tissue to prepare it to be used as a transplant," Tr. at 1569:7-13. The evidence establishes a POSA would have known cleaning processes such as those in Livesey or Goldstein could be applied before preserving a tissue graft as taught in references such as Werner or Duran. Although Dr. Kaplan testified that plasticization depends on the "entire process," Tr. at 1566:2-6, 1583:23-1584:1, the '200 patent plainly teaches that suitable "cleaning solution[s] … includ[e] known cleaning agents," PTX 1 at 9:45-49, and conclusory testimony contrary to the teachings of a patent cannot avoid a finding of obviousness. *See PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1361 (Fed. Cir. 2007) (discounting expert testimony on non-obviousness that could not "be reconciled with statements made by the inventors in the joint specification and with the prior art

[7] The parties' experts offered differing definitions of the level of ordinary skill, but it is undisputed their opinions would be the same under either definition, Tr. at 1179:16-19 (Badylak); 1520:6-9 (Kaplan), and thus the difference is immaterial.

references themselves").[8]

Moreover, Plaintiff did not offer evidence, much less legally sufficient evidence, of any applicable secondary considerations of non-obviousness. Plaintiff did not present evidence showing any skepticism, praise, unexpected results, copying, failure of others, or long-felt but unmet need for the claimed inventions. Plaintiff did not even show that its products practice all elements of the claims. Tr. at 590:3-25 (Kaplan). In addition, Plaintiff failed to present evidence establishing the required nexus between any alleged secondary considerations and the merits of the claimed inventions. *See Wyers*, 616 F.3d at 1246 ("For objective [evidence of secondary considerations] to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the *claimed invention*.") (quotations omitted); *Ormco Corp. v. Align Tech, Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006) ("[E]vidence of commercial success . . . is only significant if there is a nexus between the claimed invention and the commercial success."). Plaintiff's expert did not offer an opinion that any secondary considerations of non-obviousness are present, much less that there is the required nexus.

The evidence thus establishes that the asserted claims are obvious as a matter of law because even if there were any differences between the prior art references and the asserted claims, those differences amounted to nothing more than the use of known elements in a predictable way to achieve expected results.

D. Judgment As A Matter Of Law Should Be Granted That The Asserted Claims Are Invalid For Lack Of Enablement To Their Full Scope.

Judgment as a matter of law should be granted that the asserted claims are invalid for lack

[8] If the use of different cleaning agents affected plasticization, this would provide a further reason why the '200 patent is not enabled, as the only cleaning process disclosed in the '200 patent (Allowash), PTX 1 at 5:53-61, does not decellularize tissue grafts, Tr. 415:1-3 (Brame).

of enablement because the specification fails to enable a POSA to make and use the full scope of the claimed apparatuses and processes without undue experimentation. Whether a claim satisfies the enablement requirement "is a question of law." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1377 (Fed. Cir. 2007). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quotations omitted); *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195 (Fed. Cir. 1999).

The claims recite "plasticized soft tissue grafts" without limiting the type of plasticizer that may be used. Further, the specification lists eighteen "suitable plasticizers," PTX 1 at 7:29-52; 8:44-52, and states that other "similar water-soluble small molecular weight solutes" could also be used, *id.* at 7:46-50, either used alone or in any combinations, *id.* at 7:53-59. The specification also states "plasticizers" can be used in concentrations anywhere from 10% to 100% by weight/volume, PTX 1 at 8:59-62. This presents an extraordinary number of possibilities, and the evidence shows the specification falls far short of enabling a POSA to make and use the full scope of the claimed invention without undue experimentation.

The '200 patent's only examples of "plasticized soft tissue grafts" use glycerol as the sole plasticizer, and only at a 30% concentration. PTX 1 at 22:50-23:5; 23:35-58. The specification contains no teaching, guidance, or example of how to plasticize a soft tissue graft with any of the other seventeen listed plasticizers—let alone other possible suitable plasticizers or combinations of plasticizers—and it would take at least months of work for *each* of these materials to use it to practice the claims. Tr. at 1296:19-1298:9 (Badylak); 1587:8-19, 1588:11-20 (Kaplan). It is undisputed that these other materials are chemically different than glycerol and will behave

differently than it, and that their behavior will depend on the presence of other chemicals. Tr. at 1295:8-1296:4, 1296:11-18 (Badylak); 1584:6-18 (Kaplan). It is also undisputed that it would be necessary to experiment separately with these other materials to determine if they actually work as plasticizers—particularly plasticizers that are not removed from the internal matrix of a graft before transplantation into a human—and in what concentration. Tr. at 1296:19-1298:9 (Badylak); 1584:21-1585:22, 1588:6-20 (Kaplan). The '200 patent discloses only the exceedingly broad range of 10%-100% concentration for plasticizers, PTX 1 at 8:59-62, and offers no guidance as to what concentrations might work for what plasticizers.

The unrebutted evidence shows that, at the time the application was filed, the inventors did not actually know whether any "plasticizers" other than glycerol would work to accomplish the claimed invention, did not know which concentrations of glycerol (or any other "plasticizer") would work, and had done no testing to determine whether the other "suitable plasticizers" would actually result in a "plasticized soft tissue graft" that could be transplanted into a human without removing plasticizer from the internal matrix of the graft. *See* O'Leary Dep. Tr. at 74:09-12, 74:14-75:15, 76:20-25, 77:2-5; Wolfinbarger Dep. Tr. at 35:9-20, 35:22-36:6. Although the '200 patent states plasticizer concentrations up to 100% may be used, PTX 1 at 8:59-62, when Plaintiff actually conducted experimentation (at a later time), it determined that even "77 percent of glycerol" could not be used because "the tissue becomes hard, like a plastic." Tr. at 242:9-17 (Qin). *See Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984) (explaining that if a specification contains a significant number of inoperative claimed combinations, which "in effect forces one of ordinary skill in the art to experiment unduly to practice the claimed invention," the claimed invention lacks enablement).

Moreover, Plaintiff's expert conceded that "different amounts of [each plasticizer] may

be appropriate for plasticization," Tr. at 1584:10-18, and that it "would take months" to perform animal testing on a graft preserved with only one of the eighteen plasticizers to "determine if the graft is suitable for transplantation into a human," Tr. at 1587:22-1588:20. Defendant's expert further explained that because "each of these 18 [plasticizers] . . . have their own unique, distinct molecular structure," Tr. at 1295:20-25, a POSA would have to expend "somewhere between four to six months of effort [per molecule] and a lot of money" to determine whether and how each could be used to preserve a soft tissue graft, Tr. at 1296:19-1297:23.

Plaintiff chose to draft claims far beyond what it enabled POSAs to make and use without undue experimentation. *See* Tr. at 1296:19-1297:23 (Badylak); 1587:22-1588:20 (Kaplan). Given the evidence, a reasonable jury would need to conclude that the asserted claims were not enabled to their full scope because a POSA could not make and use the full scope of the claims without undue experimentation. *See, e.g.*, *Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380 (Fed. Cir. 2013). JMOL that the claims are invalid for lack of enablement should be granted.

E. There Is No Legally Sufficient Evidence To Support The Damages Award.

There is no legally sufficient evidence to support the jury's award of $34,741,971 in damages. The evidence supports, at most, a lump sum award of $3.8 million.

Plaintiff's damages expert, Mark Gallagher, offered opinions at trial that were contrary to well-established precedent and, therefore, cannot serve as the basis for a jury verdict. As detailed in the *Daubert* motion Defendant filed prior to trial (D.I. 251), Mr. Gallagher's opinions improperly relied on the entire market value of the accused products as the base for a running royalty. He relied on the entire value even though the evidence demonstrated that the alleged patented feature of the '200 patent was, at best, a minor driver of demand. *See, e.g.*, Tr. at 416:13-24, 418:6-20 (discussing DTX 154) (Brame); 696:3-698:6 (Gallagher); 848:15-849:25 (Erdmann); 912:24-913:18, 914:12-23 (Bachrach); 1426:18-1430:20 (discussing DTX 177)

(Martinez). Because the entire market value of the accused products can only be used when the patented feature is what motivated customers to buy the products in the first place, *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 68 (Fed. Cir. 2012), and here the evidence demonstrated that numerous non-patented features drive demand for the accused products,[9] it was improper for Mr. Gallagher to use the entire market value of the accused products without apportionment. By failing to apportion, Mr. Gallagher's opinions were contrary to the Entire Market Value Rule ("EMVR") and cannot serve as the basis for a damages award. *See, e.g.*, *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014); *LaserDynamics*, 694 F.3d at 67; *Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1318 (Fed. Cir. 2011); *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1337 (Fed. Cir. 2009) (same).

Mr. Gallagher's proposed royalty rate of 5%, which was based on an initial offer that Plaintiff made to Edwards LifeSciences, also cannot support the verdict. *First*, Edwards never even responded, suggesting the proposed royalty rate was *not* reasonable. *See, e.g.*, Tr. at 691:6-692:14 (Gallagher); 1423:5-12 (Martinez). Indeed, there is no evidence Edwards was willing to accept such a rate (and the fact that Edwards never even responded strongly suggests it was not), let alone that any other company, including Defendant, would be willing to do so. Such an initial offer cannot serve as the sole basis for a royalty rate opinion. *See, e.g., Whitserve, LLC v. Computer Packages, Inc.*, 694 F.3d 10, 29-30 (Fed. Cir. 2012) (noting that although "proposed licenses may have some value for determining a reasonable royalty in certain situations. Their evidentiary value is limited . . . by . . . the fact that patentees could artificially inflate the royalty

[9] The evidence shows non-patented features drive demand for the accused products, including the following: safety, efficacy, availability, sizes, shapes, sterility, flexibility/pliability, composition, scientific support, reputation of the company selling the products and price. *See, e.g.,*Tr. at 1426-30 (discussing DTX 177) (Martinez); *id.* at 418:6-20 (discussing DTX 154) (Brame); *id.* at 848:15-849:25 (Erdmann); *id.* at 912:23-913:18, 914:12-23 (Bachrach).

rate by making outrageous offers."); *Deere & Co. v. Int'l Harvester Co.*, 710 F.2d 1551, 1557 (Fed. Cir. 1983) (upholding the district court's decision to assign little or no probative value to a license offer). *Second*, the initial offer to Edwards was for the entire family of Preservon patents and applications, which included a far greater scope of rights than would be at issue in the hypothetical negotiation in this case, yet Mr. Gallagher did not adjust his proposed royalty rate to account for this. *See* Tr. at 690:6-20 (Gallagher); 1423:15-1424:9 (Martinez). *Third*, Mr. Gallagher relied on the proposed 5% royalty rate in the initial offer to Edwards even though prior correspondence made it clear that Edwards was interested in only a lump sum payment. *See* Tr. at 691:6-16, 693:16-20 (Gallagher); 1424:12-15 (Martinez). In sum, plaintiff's offer letter to Edwards was a legally insufficient basis for Mr. Gallagher's proposed royalty rate. As there is no other evidence in the record to support Mr. Gallagher's proposed rate of 5% opinion, it lacks any valid basis and cannot support the jury's verdict.

In contrast, Defendant's damages expert, Mr. Martinez, proposed a $3.8 million lump sum that complied with the EMVR and was fully supported by real world license agreements for technology comparable to the technology at issue in this case. *See* Tr. at 1443:1-1453:15 (discussing DTX 187 & 188). In fact, at no point did Plaintiff dispute the comparability of either license agreement Mr. Martinez relied upon. As Mr. Martinez's proposed lump sum of $3.8 million was the only valid damages opinion offered to the jury, it is the only legally sufficient evidence in the record to support a jury award. Anything award above $3.8 million is not supported by the evidence.

F. There Is No Legally Sufficient Evidence That Plaintiff Provided Constructive Notice Pursuant To 35 U.S.C. § 287(a).

It is undisputed that Plaintiff provided Defendant no actual notice of its infringement allegations prior to filing this lawsuit, and thus to collect damages for the pre-suit period Plaintiff

needed to prove that it provided constructive notice by properly marking its products in accordance with 35 U.S.C. § 287(a). *See Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996); *Nike, Inc. v. Wal-Mart Stores, Inc.*, 138 F.3d 1437, 1446 (Fed. Cir. 1998). However, there is no legally sufficient evidence that Plaintiff complied with the requirements of § 287(a) before filing its complaint. Plaintiff contends that it first began selling products covered by the '200 patent (DermACELL, OraCELL, and ArthroFLEX) in 2010. Tr. at 148:4-7 (Wilson); D.I. 1 ¶ 23. Yet Plaintiff offered no testimony or other evidence establishing that it properly marked these products with the '200 patent before filing this suit in September 2013. In fact, Plaintiff offered no evidence as to what steps it took before September 2013 to mark the products, much less that it complied with the statutory requirements for marking such that it provided adequate notice of the '200 patent to others. Therefore, there is no legally sufficient evidence to support the jury's damages verdict.

III. CONCLUSION

For the foregoing reasons, Defendant requests entry of judgment as a matter of law on the various issues discussed above.

Dated: December 18, 2014

Respectfully submitted,

/s/ William R. Poynter

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CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2014, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of such filing (NEF) to the following::

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